

REMARKS

Claims 1-8 are pending in this application. Claims 9-17 were previously withdrawn in view of the restriction requirement issued by the Examiner. Claims 1-8 remain. Claim 1 has been amended.

Claims 1-8 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 1 has been amended, as set forth above, to correspond more closely with the language used in the specification. Applicants believe that in view of these amendments the rejection under the second paragraph of § 112 has been obviated.

The Examiner has also requested clarification of the word "product". Applicants refer the Examiner to page 1, lines 14-18 of the specification wherein it is believed that this term is clearly defined.

Claims 1-8 have again been rejected under 35 U.S.C. § 102(b) as being anticipated by Gast '405 and, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Gast. Applicants submit that these rejections should be withdrawn since Gast neither teaches nor suggests the claimed invention.

Gast discloses a well-known phasic oral contraceptive including a progestin and an estrogen. According to the contraceptive regimen taught by Gast, a combination of an estrogen and a progestin is administered for 23-25 days followed by 3-5 days of estrogen-only administration. In addition to the progesting and estrogen hormones, each tablet administered in the regimen taught by Gast further includes components such as colorants, lubricants, fillers and the excipient lactose. All of these components are well known in the art of formulating oral contraceptives.

Gast nowhere teaches or suggests a formulation wherein the steroid hormone in the formulation is in non-crystalline form and wherein the hormone is stabilized in that form by the excipient. Gast also fails to provide any teaching or suggestions regarding the improved dissolution rate and release rate profiles achieved with a formulation comprising a steroid hormone stabilized in non-crystalline form by an excipient such as lactose. Gast simply lists the ingredients that comprise his Example 1 and Example 2 formulations. Only by reconstructing Gast with applicants' own teachings can the Examiner argue that this reference teaches the claimed invention. Such hindsight reconstruction is clearly impermissible and cannot form the proper basis for a rejection issued under § 102 or § 103.

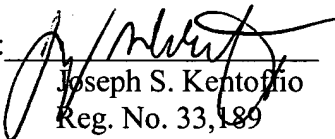
The Examiner argues that the term "comprising" as used in the claims does not exclude additional, unrecited elements or method steps. While applicants do not disagree with this position, this does not affect the claim limitation regarding the form of the hormone. Whatever elements may or may not be added, the claim requires that substantially all of the hormone be in non-crystalline form and that the hormone be stabilized in this form by the excipient. As argued above, these limitation are nowhere taught or suggested by the cited art.

In view of the foregoing, applicants believe that claims 1-8 are in condition for allowance and respectfully request that a Notice of Allowance directed to these claims be issued at the earliest possible date.

Applicants do not believe that any fees are required in connection with this Response. However, should any such fees be required, please charge Deposit Account No. 10-0750/ORT-1548/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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